



DOCKET NO.: C1039.70058US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Davis et al.
Serial No.: 10/023,909
Confirmation No.: 8458
Filed: December 18, 2001
For: USE OF NUCLEIC ACIDS CONTAINING UNMETHYLATED CPG
DINUCLEOTIDE AS AN ADJUVANT

Examiner: Jeffery S. Parkin
Art Unit: 1648

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 16th day of November, 2004.

Kristin J. Ketelhut

MAIL STOP AMENDMENT

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check in the amount of \$180 is enclosed to cover the filing fee. If the fee is insufficient, the balance may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,
Davis et al., Applicant

By:

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11/19/2004 RFEKADU1 00000019 10023909

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Docket No.: C1039.70058US00
Date: November 16, 2004
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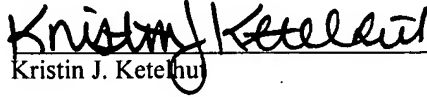
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Kristin J. Ketelhu

MAIL STOP AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180 as set forth in 37 C.F.R. §1.17(p) is enclosed.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references. The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
*C1037.70013US01	10/831,778	April 23, 2004	Bratzler et al.
*C1037.70039US01	10/816,220	April 1, 2004	McCluskie et al.
*C1037.70050US01	10/952,254	September 27, 2004	Uhlmann et al.
*C1039.70020US01	10/921,086	August 18, 2004	Krieg et al.
*C1039.70035US01	10/884,866	July 2, 2004	Krieg et al.
*C1039.70035US02	10/888,803	July 9, 2004	Krieg et al.
*C1039.70048US03	10/831,647	April 23, 2004	Krieg et al.
*C1039.70048US04	10/847,642	May 15, 2004	Krieg et al.
*C1039.70048US05	10/877,407	June 24, 2004	Krieg et al.
*C1039.70048US06	10/884,852	July 2, 2004	Krieg et al.
*C1039.70048US07	10/888,785	July 9, 2004	Krieg et al.
*C1039.70048US08	10/888,449	July 9, 2004	Krieg et al.
*C1039.70048US09	10/894,657	July 16, 2004	Krieg et al.
*C1039.70048US10	10/894,862	July 16, 2004	Krieg et al.
*C1039.70048US11	10/928,762	August 26, 2004	Krieg et al.
*C1039.70057US01	10/838,659	May 3, 2004	Davis et al.
*C1039.70058US01	10/831,775	April 23, 2004	Davis et al.
*C1039.70083US08	10/847,650	May 15, 2004	Krieg et al.
*C1039.70083US09	10/888,885	July 9, 2004	Krieg et al.
*C1039.70083US10	10/888,089	July 9, 2004	Krieg et al.
*C1040.70006US01	10/888,886	July 9, 2004	McCluskie et al.
*C1040.70012US00	10/644,267	August 20, 2003	Davis et al.
*C1041.70002US01	10/877,369	June 25, 2004	Wagner et al.

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<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
*C1041.70002US02	10/876,965	June 25, 2004	Wagner et al.
*C1041.70002US03	10/876,892	June 25, 2004	Wagner et al.
*C1041.70005US01	10/811,226	March 26, 2004	Wagner et al.
*C1041.70005US02	10/894,655	July 16, 2004	Wagner et al.
*C1041.70016US01	10/884,372	July 2, 2004	Bauer et al.
*C1041.70036US01	10/872,196	June 18, 2004	Lipford et al.

*a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

The Applicant would like to bring to the Examiner's attention the enclosed search report from a corresponding Foreign National Application.

<u>Docket No.</u>	<u>Serial No.</u>	<u>Mailing Date</u>	<u>Type of Communication</u>
C1039.70006EP00	EP 98 91 2919	12 August 2004	European Search Report

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

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By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

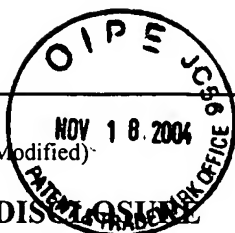
Respectfully submitted,
Davis et al., Applicant

By:



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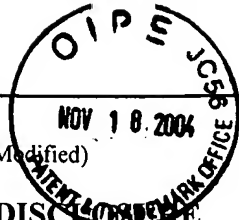
Docket No.: C1039.70058US00
Date: November 16, 2004
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FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 10/023,909		ATTY. DOCKET NO.: C1039.70058US00	
				FILING DATE: December 18, 2001		CONFIRMATION NO.: 8458	
				APPLICANT: Davis et al.			
				GROUP ART UNIT: 1648		EXAMINER: Jeffery S. Parkin	
Sheet	1	of	3				

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A52	4,578,269		Morein	03-25-1986
	A53	4,981,684		MacKenzie et al.	01-01-1991
	A54	5,178,860		MacKenzie et al.	01-12-1993
	A55	5,679,354		Morein et al.	10-21-1997
	A56	6,027,732		Morein et al.	02-22-2000
	A57	6,544,518	B1	Friede et al.	04-08-2003
	A58	6,558,670	B1	Friede et al.	05-06-2003
	A59	6,727,230	B1	Hutcherson et al.	04-27-2004
	A60	2001-0044416	A1	McCluskie et al.	11-22-2001
	A61	2002-0064515	A1	Krieg et al.	05-30-2002
	A62	2002-0091097	A1	Bratzler et al.	07-11-2002
	A63	2002-0164341	A1	Davis et al.	11-07-2002
	A64	2002-0165178	A1	Schetter et al.	11-07-2002
	A65	2002-0198165	A1	Bratzler et al.	12-26-2002
	A66	2003-0026782	A1	Krieg et al.	02-06-2003
	A67	2003-0026801	A1	Weiner et al.	02-06-2003
	A68	2003-0050261	A1	Krieg et al.	03-13-2003
	A69	2003-0050268	A1	Krieg et al.	03-13-2003
	A70	2003-0055014	A1	Bratzler	03-20-2003
	A71	2003-0087848	A1	Bratzler et al.	05-08-2003
	A72	2003-0091599	A1	Davis et al.	05-15-2003
	A73	2003-0100527	A1	Krieg et al.	05-29-2003
	A74	2003-0104523	A1	Bauer et al.	06-05-2003
	A75	2003-0139364	A1	Krieg et al.	07-24-2003
	A76	2003-0148316	A1	Lipford et al.	08-07-2003
	A77	2003-0148976	A1	Krieg et al.	08-07-2003
	A78	2003-0166001	A1	Lipford	09-04-2003
	A79	2003-0181406	A1	Schetter et al.	09-25-2003
	A80	2003-0191079	A1	Krieg et al.	10-09-2003
	A81	2003-0212026	A1	Krieg et al.	11-13-2003
	A82	2003-0224010	A1	Davis et al.	12-04-2003
	A83	2003-0232074	A1	Lipford et al.	12-18-2003
	A84	2004-0009944	A1	Tam et al.	01-15-2004
	A85	2004-0009949	A1	Krieg	01-15-2004
	A86	2004-0030118	A1	Wagner et al.	02-12-2004
	A87	2004-0038922	A1	Haensler et al.	02-26-2004
	A88	2004-0053880	A1	Krieg	03-18-2004
	A89	2004-0067905	A1	Krieg	04-08-2004
	A90	2004-0087534	A1	Krieg et al.	05-06-2004



FORM PTO-1449/A and B (Modified)

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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FILING DATE: December 18, 2001

CONFIRMATION NO.: 8458

APPLICANT: Davis et al.

GROUP ART UNIT: 1648

EXAMINER: Jeffery S. Parkin

Sheet 2 of 3

A91	2004-0087538	A1	Krieg et al.	05-06-2004
A92	2004-0092472	A1	Krieg	05-13-2004
A93	2004-0106568	A1	Krieg et al.	06-03-2004
A94	2004-0131628	A1	Bratzler et al.	07-08-2004
A95	2004-0132685	A1	Krieg et al.	07-08-2004
A96	2004-0142469	A1	Krieg et al.	07-22-2004
A97	2004-0143112	A1	Krieg et al.	07-22-2004
A98	2004-0147468	A1	Krieg et al.	07-29-2004
A99	2004-0152649	A1	Krieg	08-05-2004
A100	2004-0152656	A1	Krieg et al.	08-05-2004
A101	2004-0152657	A1	Krieg et al.	08-05-2004
A102	2004-0162258	A1	Krieg et al.	08-19-2004
A103	2004-0162262	A1	Krieg et al.	08-19-2004
A104	2004-0167089	A1	Krieg et al.	08-26-2004
A105	2004-0171150	A1	Krieg et al.	09-02-2004
A106	2004-0171571	A1	Krieg et al.	09-02-2004
A107	2004-0181045	A1	Krieg et al.	09-16-2004
A108	2004-0198688	A1	Krieg et al.	10-07-2004

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B15	EP	0 773 295	A2	Ottawa Civic Hospital	05-14-1997	
	B16	WO	98/52962	A1	Merck & Co., Inc.	11-26-1998	
	B17	WO	99/56755	A1	University of Iowa Research Foundation	11-11-1999	
	B18	WO	00/09159	A1	Aquila Biopharmaceuticals, Inc.	02-24-2000	
	B19	WO	00/15256	A2	Pasteur Merieux Serums et Vaccins	03-23-2000	Y - Abstract Only
	B20	WO	00/23105	A2	Smithkline Beecham Biologicals S.A.	04-27-2000	
	B21	WO	00/46365	A1	Virginia Commonwealth University	08-10-2000	
	B22	WO	00/62800	A2	Smithkline Beecham Biologicals S.A.	10-26-2000	
	B23	WO	02/28428	A2	Aventis Pasteur	04-11-2002	Y- Abstract Only
	B24	WO	03/026688	A1	Pharmaderm Laboratories, Ltd.	04-03-2003	
	B25	WO	2004/007743	A2	Coley Pharmaceutical GMBH	01-22-2004	
	B26	WO	2004/039829	A2	Coley Pharmaceutical Group, Ltd.	05-13-2004	



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				APPLICANT: Davis et al.	
				GROUP ART UNIT: 1648	EXAMINER: Jeffery S. Parkin
Sheet	3	of	3		

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
	C14	DASS et al., Immunostimulatory activity of cationic-lipid-nucleic-acid complexes against cancer. J Cancer Res Clin Oncol. 2002 Apr;128(4):177-81. Epub 2002 Feb 23. Review. Abstract Only.		
	C15	O'HAGAN et al., Recent developments in adjuvants for vaccines against infectious diseases. Biomol Eng. 2001 Oct 15;18(3):69-85. Review. Abstract Only.		
	C16	O'HAGAN et al., Recent developments in vaccine delivery systems. Curr Drug Targets Infect Disord. 2001 Nov;1(3):273-86. Review. Abstract Only.		
	C17	McCLUSKIE et al., Mucosal immunization of mice using CpG DNA and/or mutants of the heat-labile enterotoxin of Escherichia coli as adjuvants. Vaccine. 2001 Jun 14;19(27):3759-68.		
	C18	RAZ et al., Potential role of immunostimulatory DNA sequences (ISS) in genetic immunization and autoimmunity. American College of Rheumatology 60th National Scientific meeting and Association of Rheumatology Health Professional 31st National Scientific meeting, Orlando, Florida, October 18-22, 1996. Abstracts. Arthritis Rheum. 1996 Sep;39(9 Suppl): 615.		
	C19	SCHIRMBECK et al., Antigenic epitopes fused to cationic peptide bound to oligonucleotides facilitate Toll-like receptor 9-dependent, but CD4+ T cell help-independent, priming of CD8+ T cells. J Immunol. 2003 Nov 15;171(10):5198-207.		
	C20	SINGH et al., Recent advances in veterinary vaccine adjuvants. Int J Parasitol. 2003 May;33(5-6):469-78. Review. Abstract Only.		
	C21	SINGH et al., Recent advances in vaccine adjuvants. Pharm Res. 2002 Jun;19(6):715-28. Review. Abstract Only.		
	C22	SINGH et al., Advances in vaccine adjuvants. Nat Biotechnol. 1999 Nov;17(11):1075-81. Review.		
	C23	SJOLANDER et al., Kinetics, localization and isotype profile of antibody responses to immune stimulating complexes (iscoms) containing human influenza virus envelope glycoproteins. Scand J Immunol. 1996 Feb;43(2):164-72.		
	C24	SJOLANDER et al., Iscoms containing purified Quillaja saponins upregulate both Th1-like and Th2-like immune responses. Cell Immunol. 1997 Apr 10;177(1):69-76.		
	C25	ZHAO et al., Effect of different chemically modified oligodeoxynucleotides on immune stimulation. Biochem Pharmacol. 1996 Jan 26;51(2):173-82.		

EXAMINER:	DATE CONSIDERED:
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. __, filed __, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]